K04-2435

CooperVision

OCT 2 6 2004

Premarket Notification

Cooper Prosthetic Polymacon

510(k) Summary

1. **SUBMITTER:**

Submitted on Behalf of:

▪ Company Name:	CooperVision Manufacturing, Ltd.
▪ Address:	Unit 2, South Point Hamble SO3 4RF Southampton UK
▪ Phone:	011 44 2380 605200
▪ Fax:	011 44 2380 605299

2. **CONTACT PERSON:** Bonnie Tsymbal

▪ Company Name:	CooperVision, Inc.
▪ Address:	711 North Road Scottsville, NY 14546
▪ Phone:	(585) 264-3210
▪ Fax:	(585) 889-5688

3. **DATE SUMMARY PREPARED:** **September 7th, 2004**

4. **DEVICE IDENTIFICATION:**

▪ Trade Name:	Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens
▪ Common Name:	Hydrophilic Soft Contact Lens
▪ Classification	Lenses, Soft Contact, Daily Wear 86LPL
▪ Device Classification:	Class II (21 CFR 886.5925)

5. **DEVICE DESCRIPTION:**

The Cooper Prosthetic Lens (polymacon) Soft (hydrophilic) Contact Lenses are available as spherical lenses. The lens material, polymacon, is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) which is cross linked with ethyleneglycol dimethacrylate. When hydrated, the lens consists of 62.0% HEMA and 38.0% water by weight when immersed in normal saline. The lenses are made by modifying the uncolored polymacon lens by affixing a colored pigment on that portion of the front surface that corresponds to the iris. The colored pigments consist of carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide.

Cooper Prosthetic Lenses are hemispherical shells with the following dimensions:

Diameter:	14.0mm to 15.0mm
Base Curve:	8.0mm to 9.5mm
Center Thickness:	0.05mm to 0.40mm (varies with power)
Lens Powers:	-20.00 to +20.00D

The physical/optical properties of the **Cooper Prosthetic Lenses** are:

Refractive Index:	1.43
Light Transmittance:	>90% (open pupil)
Surface Character:	Hydrophilic
Water Content:	38%
Oxygen Permeability:	8.0×10^{-11} (cm^2/sec) (ml O_2/ml x mmHg) at 35°C (Fatt method for determination of oxygen permeability)

6. INTENDED USE:

The Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons that may exhibit astigmatism up to 2.00 diopters that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

7. SUBSTANTIAL EQUIVALENCE:

Characteristic	Cooper Prosthetic UK Lathed Base (New Device)	Cooper Prosthetic *UK Molded Base* K984259	Cooper Prosthetic Gelflex Lathed Base K010126
Material	Polymacon	Polymacon	Polymacon
Material Classification	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1
Indications for Use	Daily Wear To enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia	Daily Wear To enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia	Daily Wear To enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia
Water Content	38%	38%	38.6%
Light Transmittance	>97%	>97%	>95%
Dk (35° C)	8.0×10^{-11}	8.0×10^{-11}	8.0×10^{-11}
Refractive Index	1.43	1.43	1.43
Powers	-20.00 to +20.00 D	-20.00 to +20.00 D	-20.00 to +20.00 D
Colorants	carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide	carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide	carbazole violet, chromium oxide green, dihydrodinaphto brown, dihydrodioxo yellow, phthalocyanine green, iron oxide red, iron oxide brown, iron oxide black, phthalocyanine blue, and titanium oxide
Tint Process	Pad Printing Post Lens Forming	Pad Printing Post Lens Forming	Pad Printing Post Lens Forming
Manufacturing Method	Lathe Cut	Cast Molded	Lathe Cut

8. PRECLINICAL INFORMATION:

The results of toxicology testing, including Ocular Irritation, Cytoxicity and Systemic Toxicity have demonstrated that the subject lens is non-toxic.

An Monomer Extractable Study was conducted to assess the suitability of using an alternative polymacon base lens for Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens. Samples were analyzed to determine the levels of 2-HEMA and EGDMA remaining in the lathe-cut polymacon lens. The test lenses indicated that the levels of residual 2-HEMA and EDGMA found were in compliance with specifications, and equivalent to that seen in the current product..

The physical, optical and chemical properties of the subject lens are equivalent to the predicate device.

9. CLINICAL DATA:

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens. This determination was based on the following:

- Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens has demonstrated to be substantially equivalent to the predicate Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens (K984259) and (K010126).

10. CONCLUSION:

The information provided in this 510(k) establishes that the Cooper Prosthetic (polymacon) Soft (hydrophilic) Contact Lens is equivalent in optical, chemical and physical properties of the predicate device and does not raise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2004

CooperVision, Inc.
c/o Ms. Bonnie Tsymbal
711 North Road
Scottsville, NY 14546

Re: K042435
Trade/Device Name: Cooper® Prosthetic (polymacon) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Hydrophilic Soft Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: September 7, 2004
Received: September 8, 2004

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CooperVision
Regulatory Affairs
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Indication for Use Statement

510(k) Number:

Device Name: Cooper® Prosthetic (polymacon) Soft (hydrophilic) Contact Lenses

Indication for Use:

The Cooper® Prosthetic (polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear to enhance or alter the apparent color of the eye, including ocular masking, either in sighted or non-sighted eyes that require a prosthetic contact lens for management of conditions such as corneal, iris, or lens abnormalities. The lens may also be prescribed for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons that may exhibit astigmatism up to 2.00 diopters that does not interfere with visual acuity or for occlusive therapy for conditions such as diplopia, amblyopia or extreme photophobia.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter _____ (Per 21 CFR 801 Subpart C)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K042435